

REMARKS

Claims 1, 3-13, and 28 are pending in the application. Claims 1, 6, and 8-13 remain rejected, and claims 3-5 and 28 are newly rejected as being anticipated by Fong et al., US 2002/0071832; claims 1, 6, and 7 remain rejected under 35 U.S.C. § 103(a) over Fong et al., US 2002/0071832; and claims 1, 3-6, 8, 9, and 28 remain rejected under 35 U.S.C. § 103(a) over Kooby et al., FASEB J. 13:1325-1334, 1999, in view of Rodgers and McCall, Brit. J. Surg. 87:1142-1155, 2000. Each of the rejections is addressed below.

Applicants first would like to thank the Examiner for the helpful telephone interview with the undersigned on April 14, 2008. Consistent with the interview, Applicants are submitting herewith arguments in response to the prior art-based rejections that are briefly stated as follows:

- Fong et al., US 2002/0071832, does not expressly anticipate the present claims, as Fong does not teach the treatment of metastases.
- Fong et al., US 2002/0071832, does not inherently anticipate the present claims, as carrying out the methods of Fong does not necessarily result in the effects of the methods of the present claims (i.e., treatment of metastases).
- The presently claimed invention (treatment of metastases) may be considered as a species of the teaching of Fong (treatment of cancer), and non-obvious species may be patentable over the teaching of a genus.
- The presently claimed invention is not obvious over Fong and Wong (or the combination of Kooby and Rodgers), as there is no suggestion or basis for considering in Fong and Wong (or the combination of Kooby and Rodgers) that administration of a virus to a tumor bed would result in treatment of metastasis.

The rejections in the Office Action are now addressed.

Rejection under 35 U.S.C. § 102(e)

Claims 1, 6, and 8-13 remain rejected, and claims 3-5 and 28 are newly rejected, under 35 U.S.C. § 102(e) as being anticipated by Fong et al., US 2002/0071832. Applicants respectfully request reconsideration of this rejection, for the reasons discussed below.

In making this rejection, the Examiner states that “the method steps of resecting a tumor and then applying lytic virus are the same as those in Fong” and “Fong’s method steps would have treated metastatic cancer distal to the site of resection and would treat cancer that is present in the lymphatic system of the patient” (page 3). Further, the Examiner cites case law to support the statement that “it is a general rule that merely discovering and claiming a new benefit to an old process cannot render the process again patentable.” In response to Applicants’ prior submission, the Examiner states “Fong’s method... would have treated metastatic cancer that was distal to the site of resection whether Fong realized it or not” (page 5). Based on the above, it appears that this rejection is based on the position that the method of the present claims is inherently taught by Fong.

In response, Applicants submit that Fong does not mention the treatment of metastases at a site distal to the site of surgical resection of a tumor and, thus, Fong does not expressly anticipate the present claims. Applicants further submit that inherent anticipation does not apply. In particular, M.P.E.P. 2112 states “the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic,” (emphasis in original; citations omitted) and that an “allegedly inherent characteristic must

necessarily flow from the teachings of the applied prior art" (M.P.E.P. 2112 (IV); citations omitted; emphasis added). Further, M.P.E.P. 2112 states that "the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." This is consistent with the Federal Circuit's discussion of inherency in *Mehl/Biophile International Corp. v. Milgraum*, 192 F.3d 1362, 52 U.S.P.Q.2d 1303 (Fed. Cir. 1999). In this case, the Court states that "[u]nder the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates" and that "occasional results are not inherent."

Applying these principles to the present case, Fong does not inherently teach the present invention, as carrying out the methods of Fong would not necessarily result in the treatment of the metastases that are the focus of the present claims, as not all tumors treated according to Fong would have produced metastases. Therefore, treatment of metastasis at a site distal from the site of surgical resection would not "necessarily flow" from carrying out the method of Fong, and such a result may be considered, at best, to be "occasional," which, as discussed above, is not sufficient to establish inherency. Thus, as the teachings of Fong do not teach the presently claimed method, either expressly or inherently, Applicants respectfully request that this rejection be withdrawn.

Another way to view this matter is to consider that Fong teaches a genus of treating cancer, in general, but Fong does not teach the species of treating metastases, as is now claimed. As discussed specifically with respect to the chemical arts, a prior art teaching of genus may only anticipate a species if the species can at once be envisaged from the genus. M.P.E.P. 2131.02. Analogizing this standard to the present case, there is nothing in Fong that would result in one of

ordinary skill in the art at once envisaging what is now claimed. In particular, the killing of cells at a locus of administration is so different from killing cells distal to the locus of administration, that the latter certainly would not be considered in view of the former. It was simply not known prior to the present invention that administered virus could indeed move to the site of a metastasis. Further, in the chemical context, anticipation may be found if the components of the species are set forth within the genus, and it only requires a mixing and matching of set forth options to arrive at the claimed species. This does not apply in the present case, as there is no teaching whatsoever of treating metastasis in Fong.

Applicants further would like to comment upon claims 4, 5, and 28, which specify the treatment of lymphatic metastases. Fong nowhere mentions the treatment of any metastases, let alone lymphatic metastases, and thus certainly does not expressly anticipate this claim. Fong also does not inherently anticipate this claim, as carrying out the method of Fong does not necessarily result in the treatment of such metastases, as not all cancers treated using the method Fong would have them. Consistent with the reasoning set forth above, lymphatic metastases are a particular species of cancer, and the genus of Fong (any cancer, as interpreted by the Examiner) does not anticipate the species.

In view of the above, Applicants respectfully request reconsideration of the anticipation rejection over Fong.

Rejections under 35 U.S.C. § 103(a)

Rejection over Fong et al., US 2002/0071832, in view of Wong et al., Human Gene Therapy 12(3):253-265, 2001

Claims 1, 6, and 7 remain rejected for obviousness over Fong et al., US 2002/0071832, in combination with Wong et al., Human Gene Therapy 12(3):253-265, 2001. This rejection is respectfully traversed.

In this rejection, the Examiner makes note of the anticipation rejection based on Fong, stating that the Fong method includes the same steps as those of the present claims, and states “the method of Fong does result in the method of the present invention because Fong’s teaching is applicable to cancer patients regardless if they had metastatic cancer or not.” Further in maintaining this rejection, the Examiner states that “whether or not Fong realized that the method of resecting a tumor and administering oncolytic virus at the site treats metastatic cancer that is distal to the resection site, the method steps are the same and would have treated cancer patients that have metastatic cancer.” With respect to Wong, the Examiner states “Wong et al. teach that NV 1023 can be used to treat cancer and thus, an artisan would have been motivated to use NV 2023 with the method of Fong et al.”

As is discussed above, Fong does not anticipate the present claims, as Fong does not expressly teach the treatment of metastases, and inherency also cannot be found, as carrying out the method of Fong does not necessarily result in the effects of the method of the present claims (see above). In view of this, Applicants respectfully submit that the teachings of Fong should be considered only with respect to killing of cancer cells at the site of surgical resection and virus administration. As there is no mention in either of Fong or Wong of the treatment of metastases

that are present at a site distal to the site of surgical resection, Applicants request that this rejection be reconsidered and withdrawn.

Applicants also submit that it was not known prior to the present invention that virus administered to a surgical bed could travel from the site of the surgical bed by any means (including via the lymphatic system). Thus, as this general concept was not known, Fong does not provide any suggestion or motivation to carry out the presently claimed invention. Such a suggestion or motivation also does not come from Wong, which was cited as describing a particular attenuated, replication-competent, oncolytic herpes simplex virus, NV1023.

In view of the above, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over the Fong and Wong publications be withdrawn.

Rejection over Koob et al., FASEB J. 13:1325-1334, 1999, in view of Rodgers and McCall, Brit. J. Surg. 87:1142-1155, 2000

Claims 1, 3-6, 8, 9, and 28 remain rejected for obviousness over Koob et al., FASEB J. 13:1325-1334, 1999, in view of Rodgers and McCall, Brit. J. Surg. 87:1142-1155, 2000.

Applicants respectfully request reconsideration of this rejection for the reasons discussed below.

In a prior reply, Applicants submitted that the focus of Koob was to reduce local recurrences, and that there was no suggestion or motivation to treat metastases, such as lymphatic metastases as taught by Rodgers. In maintaining the rejection, the Examiner states “an artisan would have arrived at the claimed invention, using the teachings of Koob et al., in view of Rodgers et al.” Also in the rejection, and referring to M.P.E.P. 2112, the Examiner states

“whether or not the art at the time of filing realized the unknown benefit of treating metastatic cancer in lymph nodes is not necessary to show obviousness.”

In view of the above, it is evident that the obviousness rejection is based on the concept of inherency. Thus, in response to the rejection, Applicants refer to the discussion above concerning inherency. As discussed above, in order for inherency to apply, an “allegedly inherent characteristic must necessarily flow from the teachings of the applied art” and “the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic” (M.P.E.P. 2112). In carrying out the approach of Kooby, the method of the present invention, requiring the treatment of metastases, may not take place in some instances, when there are no metastases to treat. Thus, as a required feature of the present invention (treatment of metastases) is not necessarily present in the method of Kooby, the principles of inherency do not apply.

Further in the rejection, the Examiner states “all that is required to make the claims obvious is that the art needs to show that the two steps of resection and administration of virus be known and have a rational to be combined. Kooby et al. provide motivation of combining two types of cancer therapy. As such, the claims are obvious.” In response, Applicants respectfully submit that the resection and administration of Kooby are done for a different purpose than in the present invention: prevention of local recurrence (Kooby) and treatment of metastases (the present invention). Applicants’ invention thus provides a new use. This use would not have been obvious over the teachings of Kooby and Rodgers because, as discussed above, these references provide no teaching or suggestion of the treatment of metastases. Also as discussed above, prior to the present invention, it simply was not known that virus administered to a

surgical bed could travel from the site of the surgical bed by any means (including via the lymphatic system).

Thus, as the presently claimed invention is not inherent in the teachings of Kooby and Rodgers, and because there is no suggestion or motivation to treat metastases in the cited references, Applicants request that this rejection be withdrawn.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. Please apply any charges not covered or any credits to Deposit Account No. 03-2095.

Respectfully submitted,

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